Claims:

1. An opioid formulation for use in a method of providing analgesia to a patient comprising the steps of:

continuously inhaling the formulation using a pulmonary drug delivery device to produce analgesia; and

stopping inhalation when satisfactory analgesia is achieved or at the onset of a side effect;

wherein the formulation comprises an effective amount of at least one rapid-onset opioid; and a pharmaceutically acceptable carrier, the concentration and type of each opioid, and amount of and particle size of the formulation delivered from the device on each inhalation, being selected so that, during inhalation, analgesia is achieved before the onset of said side effect, and the onset of said side effect occurs before the onset of toxicity, and so that the maximum total opioid plasma concentration does not reach toxic levels, whereby the onset of said side effect can be used by the patient to terminate inhalation to avoid toxicity.

2. The formulation of claim 1 wherein the formulation is dispensed by the pulmonary drug delivery device at a mass medium aerodynamic diameter of from 1 to 5 microns.

3. The formulation of claim 2 wherein the formulation is dispensed by the pulmonary drug delivery device at a mass medium aerodynamic diameter of from 1 to 3 microns.

4. The formulation of claim 3 wherein the formulation is dispensed by the pulmonary drug delivery device at a mass medium aerodynamic diameter of from 1.5 to 2 microns.

5. The formulation of claim 1 wherein the maximum total opioid plasma concentration at the onset of side effect is no less than 66% of the maximum total opioid plasma concentration.

6. The formulation of claim 5 wherein the maximum total opioid plasma concentration at the onset of side effect is no less than 80% of the maximum total opioid plasma concentration.

7. The formulation of claim 1 wherein the at least one rapid-onset opioid is chosen from fentanyl, alfentanil, sufentanil and remifentanil.

8. The formulation of claim 7 wherein the at least one rapid-onset opioid is chosen from fentanyl and alfentanil.

9. The formulation of claim 1 further comprising an effective amount of at least one sustained-effect opioid to provide sustained relief, wherein the concentration and type of each opioid in the formulation is selected so that, during inhalation, analgesia is achieved before the onset of said side effect, and the onset of said side effect occurs before the onset of toxicity, and so that the maximum total opioid plasma concentration does not reach toxic levels, whereby the onset of said side effect can be used by the patient to terminate inhalation to avoid toxicity.

10. The formulation of claim 9 wherein the at least one sustained-effect opioid is chosen from morphine, morphine-6-glucuronide, methadone, hydromorphone, meperidine, an opioid encapsulated in a biocompatible carrier that delays release of the drug at the lung surface, and a liposome encapsulated opioid.

11. The formulation of claim 10 wherein the liposome encapsulated opioid is liposomally encapsulated fentanyl.

12. The formulation of claim 11 wherein the at least one sustained-effect opioid is chosen from morphine and liposomally encapsulated fentanyl.

13. The formulation of claim 11 wherein the opioids in the formulation consist of fentanyl and liposomally encapsulated fentanyl.

14. The formulation of claim 13 wherein the ratio of concentration of liposomally encapsulated fentanyl to fentanyl is from 1:2 to 6:1.

15. The formulation of claim 14 wherein the ratio of concentration of liposomally encapsulated fentanyl to fentanyl is from 1:1 to 5:1.

16. The formulation of claim 15 wherein the ratio of concentration of liposomally encapsulated fentanyl to fentanyl is from 2:1 to 4:1.

17. The formulation of claim 16 wherein the ratio of concentration of liposomally encapsulated fentanyl to fentanyl is about 3:1.

18. The opioid formulation of claim 13 wherein the total opioid concentration is from 250 to 1500 mcg/ml.

19. The opioid formulation of claim 13 containing liposomally encapsulated fentanyl in a concentration of from 250 to 1500 mcg/ml.

20. The opioid formulation of claim 13 containing fentanyl in a concentration of from 100 to 750 mcg/ml.

21. The opioid formulation of claim 13 wherein the total opioid concentration is about 500 mcg/ml, the fentanyl concentration is about 200 mcg/ml and the liposomally encapsulated fentanyl concentration is about 300 mcg/ml.

22. The formulation of claim 13 wherein the concentration of fentanyl, and amount and particle size of the formulation delivered from the device, is selected so that from 4 to 50 mcg/min. of fentanyl is deposited in the lungs during inhalation.

23. The formulation of claim 22 wherein the concentration of fentanyl, and amount and particle size of the formulation delivered from the device, is selected so that from 10 to 20 mcg/min. of fentanyl is deposited in the lungs during inhalation.

24. The formulation of claim 23 wherein the concentration of fentanyl, and amount and particle size of the formulation delivered from the device, is selected so that about 15 mcg/min. of fentanyl is deposited in the lungs during inhalation.

25. The formulation of claim 13 wherein the concentration of liposomally encapsulated fentanyl, and amount and particle size of the formulation delivered from the device, is selected so that from 5 to 150 mcg/min of liposomally encapsulated fentanyl is deposited in the lungs during inhalation.

26. The formulation of claim 25 wherein the concentration of liposomally encapsulated fentanyl, and amount and particle size of the formulation delivered from the device, is selected so that from 10 to 90 mcg/min of liposomally encapsulated fentanyl is deposited in the lungs during inhalation.

27. The formulation of claim 26 wherein the concentration of liposomally encapsulated fentanyl, and amount and particle size of the formulation delivered from the device, is selected so that from 15 to 60 mcg/min of liposomally encapsulated fentanyl is deposited in the lungs during inhalation.

28. The formulation of claim 27 wherein the concentration of liposomally encapsulated fentanyl, and amount and particle size of the formulation delivered

from the device, is selected so that from 20 to 45 mcg/min of liposomally encapsulated fentanyl is deposited in the lungs during inhalation.

29. The formulation of claim 10 wherein the opioids in the formulation consist of alfentanil and morphine.

30. The formulation of claim 29 containing alfentanil in a concentration of from 300 to 6700 mcg/ml.

31. The formulation of claim 29 wherein the concentration of alfentanil, and amount and particle size of the formulation delivered from the device, is selected so that from 100 to 500 mcg/min of alfentanil is deposited in the lungs during inhalation.

32. The formulation of claim 31 wherein the concentration of alfentanil, and amount and particle size of the formulation delivered from the device, is selected so that about 250 mcg/min of alfentanil is deposited in the lungs during inhalation.

33. The formulation of claim 29 containing morphine in a concentration of from 650 to 13350 mg/ml.

34. The formulation of claim 29 wherein the concentration of morphine, and amount and particle size of the formulation delivered from the device, is selected so that from 100 to 2000 mcg/min of morphine is deposited in the lungs during inhalation.

35. The formulation of claim 34 wherein the concentration of morphine, and amount and particle size of the formulation delivered from the device, is selected so that from 200 to 1000 mcg/min of morphine is deposited in the lungs during inhalation.

36. The formulation of claim 35 wherein the concentration of morphine, and amount and particle size of the formulation delivered from the device, is selected so that about 500 mcg/min of morphine is deposited in the lungs during inhalation.

37. A method of administering an opioid formulation to provide analgesia to a patient, comprising the steps of:

continuously inhaling the formulation using a pulmonary drug delivery device to produce analgesia; and

stopping inhalation when satisfactory analgesia is achieved or at the onset of a side effect;

wherein the formulation comprises an effective amount of at least one rapid-onset opioid and a pharmaceutically acceptable carrier; the concentration and type of each opioid, and amount of and particle size of the formulation delivered from the device on each inhalation, being selected so that, during inhalation, analgesia is achieved before the onset of said side effect, and the onset of said side effect occurs before the onset of toxicity, and so that the maximum total opioid plasma concentration does not reach toxic levels, whereby the onset of said side effect can be used by the patient to terminate inhalation to avoid toxicity.

38. The method of claim 37 wherein the pulmonary drug delivery device comprises:

a container containing said formulation;

means for forming the formulation into particles having a mass medium aerodynamic diameter of from 1 to 5 microns for delivery to a patient;

an outlet through which the formulation is dispensed; and

means for dispensing said formulation through said outlet;

wherein the device is adapted to dispense the formulation only through an exercise of conscious effort by the patient.

39. A pulmonary drug delivery device comprising:

a container containing a formulation comprising an effective amount of at least one rapid-onset opioid and a pharmaceutically acceptable carrier;

means for forming the formulation into particles having a mass medium aerodynamic diameter of from 1 to 5 microns for delivery to a patient;

an outlet through which the formulation is dispensed; and

means for dispensing said formulation through said outlet;

wherein the device is adapted to dispense the formulation only through an exercise of conscious effort by the patient; and the concentration and type of each opioid, and amount of and particle size of the formulation delivered from the device on each inhalation, is selected so that, during inhalation, analgesia is

achieved before the onset of said side effect, and the onset of said side effect occurs before the onset of toxicity, and so that the maximum total opioid plasma concentration does not reach toxic levels, whereby the onset of said side effect can be used by the patient to terminate inhalation to avoid toxicity.

40. The device of claim 39 further comprising delivery rate controlling means for limiting the rate at which the formulation is dispensed to below a selected threshold.

41. The device of claim 39 wherein said device has a weight ranging from 250 to 2500 grams.

42. The device of claim 39 wherein said outlet comprises a fenestration which must be sealed by the lips of the patient in order for the formulation to be dispensed.

43. The device of claim 39 wherein said dispensing means is breath actuated.

44. An opioid administration kit comprising:

a pulmonary drug delivery device comprising a container; means for forming a formulation contained in the container into particles having a mass medium aerodynamic diameter of from 1 to 5 microns for delivery to a patient; an outlet through which the formulation is dispensed; and means for dispensing said formulation through said outlet; wherein the device is adapted to dispense the formulation only through an exercise of conscious effort by the patient; and

an opioid formulation contained in the container or for receipt by the container, said formulation comprising an effective amount of at least one rapid-onset opioid and a pharmaceutically acceptable carrier; the concentration and type of each opioid, and amount of and particle size of the formulation delivered from the device on each inhalation, being selected so that, during inhalation, analgesia is achieved before the onset of said side effect, and the onset of said side effect occurs before the onset of toxicity, and so that the maximum total opioid plasma concentration does not reach toxic levels, whereby the onset of said side effect can be used by the patient to terminate inhalation to avoid toxicity; and

instructions for using said kit comprising the steps of continuously inhaling the formulation using a pulmonary drug delivery device to produce analgesia;

and stopping inhalation when satisfactory analgesia is achieved or at the onset of a side effect.

45. The kit of claim 44 wherein said instructions further comprises the step of filling the device with said opioid formulation prior to administration.

46. The use of a formulation according to claim 1 in the manufacture of a medicament for providing analgesia to a patient.

47. The use of a formulation according to claim 1 in providing analgesia to a patient.